REMARKS

Claims

Claims 1–2 and 4–23 are pending. Applicants acknowledge the PTO's reconsideration of the restriction requirement. Claim 3 is cancelled by this paper. Accordingly, claims 1, 2, 4–11 and 20–23 are under consideration and claims 12–19 are withdrawn from consideration due to restriction/election.

Amendments

The claims have been amended to use language in accordance with conventional US practice and to correct obvious typographical errors.

Amended claim 1 incorporates the subject matter of claim 3, which is now cancelled without prejudice or disclaimer. The amendment of claims 4 and 5 is self-explanatory.

It is respectfully submitted that the amendments do not recite new matter. Entry thereof is respectfully requested.

IDS

Copies of foreign patent references cited in the PTO-1449 filed March 30, 2005 are enclosed herewith for the Examiner's review. With respect to WO02074962 (PCT/JP02/02330) cited in the PTO-1449, a copy of US20040198959A1, which corresponds to the Japanese publication, is enclosed herewith. Favorable consideration is respectfully requested.

Oath

A supplemental oath is enclosed herewith, rendering the objection thereof moot.

Formal objections

The Examiner is thanked for her careful review of the disclosure and the claims. The objections are moot in view of the aforementioned amendments.

Rejections under §112, ¶2

The forgoing amendments obviate the Examiner's contentions raised under items (a), (b) and (c) of this rejection. Applicants' amendment of the claims is not to be construed as acquiescence to any rejection.

Applicants respectfully traverse the alleged indefiniteness in the temporal relationship

between the claimed treatment regimen (with an HDAC inhibitor) and level of histone acetylation (see, part (a) under item 12 at page 6 of the Office Action). It is submitted that the metes and bounds of the intended endpoint, which is dependent upon the level of histone acetylation compared to a reference standard, is well-understood by those of ordinary skill in the art. Insofar as the level is lower to a reference standard, the results can be interpreted in light of what is claimed herein.

With respect to the rejection of claim 10, Applicants further submit that for a skilled artisan, who is in possession of the claimed antibody molecules and is knowledgeable with respect to the techniques for the utilization thereof, for example in *in vitro* or *in vivo* applications, what is claimed herein is sufficiently definite.

As to the claim term "contacting," as recited herein, it appears that the Examiner is questioning the breadth of this term. However, the courts have long held that breadth is not indefiniteness. *In re Gardner et al.,* 166 USPQ 138 (CCPA 1970).

Withdrawal of the rejection is respectfully requested.

Enablement rejection under §112, ¶1

Enablement

The German Collection of Microorganisms and Cell Cultures (DSMZ) is a recognized International Depositary Authority (IDA) and thus deposits made therein satisfies the requirements under 37 CFR §1.803. The molecules of the present invention have been deposited at DSMZ under the provisions under the Budapest treaty. Moreover, all restrictions relating to the public access of the deposited molecules will be irrevocably removed upon grant of a patent to this application.

Written description

The rejection of claims 20–23 for alleged lack of written description of the antibody species recited therein is respectfully traversed. Applicants' specification explicitly teaches that the T25 antibody "is obtainable from the cell line G2M-T25-H4ac deposited at DSMZ" and that the T52 antibody "is obtainable from the hybridoma cell line termed G2M-T52-ac deposited at DSMZ." The specification further teaches that the antibodies are "monoclonal" in lineage. See also, claims 4 and 5. Insofar as the lineage of the antibody species is well-described and the molecules claimed herein are publically available, the statutory requirements under §112, ¶1 are fully satisfied.

Applicants' claims are in conformance with the precedent set forth in *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004). The *Noelle* court explicitly stated that the "disclosure of an antigen fully characterized by its structure, formula, chemical name, physical

properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen." In view of the detailed disclosure in Applicants' own specification regarding the claimed antigen species (for example, histone H4, such as, for example human histone having the Swiss Prot Accession Number P02304), it is respectfully submitted that Applicant was in possession of the claimed antibody molecules as of the filing date of the present application. See, page 8, ¶2. Applicants' specification provides further guidance regarding the structure of acetylated and deacetylated histone molecules, for example, a disclosure of amino acid residues in histone H4 polypeptides which are acetylated is fully provided. To this end, the specification explicitly teaches that the "acetylated histone H4 may occur at any lysine residue of the amino acid sequence, preferably the acetylation is at lysines at position 6, 9, 13 and/or position 17 of human histone H4." This disclosure provides more than adequate guidance as to the structure of the molecules to which the antibodies of the present invention are directed.

As to the antibody molecules recited in the dependent claims, the written description of such molecules is provided by the explicit disclosure of the antigens (i.e., polypeptides which are fully disclosed in the sequence disclosure) to which they bind and/or do not bind. For example, the present specification teaches that an antibody according to the present invention binds to peptides having sequences as shown in SEQ ID NO:1, SEQ ID NO:10 and SEQ ID NO:11 but not to a peptide having the sequence as shown in SEQ ID NO:2. It is further taught that such antibodies may bind to peptides having sequences as shown in SEQ ID NO:4, SEQ ID NO:5 and SEQ ID NO:6. The antibody T52 is disclosed as a representative example of such antibody. See, page 8, ¶3.

In a related embodiment, the present specification teaches that other antibody molecules according to the present invention bind to peptide having the sequence as shown in SEQ ID NO:1 but not to peptides having the sequences as shown in SEQ ID NO:2, SEQ ID NO:10 and SEQ ID NO:11 and that such antibodies may additionally bind to peptides having the sequences as shown in SEQ ID NO:4 and SEQ ID NO:5 but not to a peptide having the sequence as shown in SEQ ID NO:6. The antibody molecule T25 and the antigens that bind thereto are taught to be representative of the claimed genus of antibodies. See, the paragraph bridging pages 8 and 9 and of the originally-filed specification.

It is therefore respectfully submitted that the disclosure in the present specification more than adequately satisfies the written description requirements set forth under §112, ¶1. Withdrawal of the rejection is respectfully requested.

Rejection under §102

Claims 1, 3, and 6–11 are rejected under §102(a) as allegedly anticipated by Heinzel (EP

02021228.8). This rejection is respectfully traversed.

Inasmuch as the cited foreign priority document EP02021228.8 was not in itself published, and that WO/2004/027418, which claims priority thereto, was published (publication date: April 1, 2004) after the PCT filing date of the present application (PCT/EP03/10842 filed September 30, 2003), it is disqualified as prior art under §102(a). See, *supra* with respect to request for the correction of the international filing date of the present application. Withdrawal of the rejection is respectfully requested.

Rejection under §103

Claims 1, 2, and 6–9 and 11 are rejected under §103(a) as allegedly being rendered obvious by Butler (*Clinical Cancer Research*, 2001) in view of Marks (*Nature Reviews Cancer*, 2001). This rejection is respectfully traversed.

This rejection is rendered moot in view of Applicants' amendment of the claims, i.e., claim 3 was not rejected under this section and the incorporation of the subject matter of claim 3 into independent claims 1 and 11 obviates the rejection.

No fees are believed to be due with this response; however, the Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

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